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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,084	05/09/2001	Normand Brisson	ODDY 001	6912

7590 09/23/2003
Isaac A. Angres
Suite 301
2001 Jefferson Davis Highway
Arlington, VA 22202

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,084

Applicant(s)

BRISSON ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed June 23, 2003, has been entered.

Claims 1-6 are currently amended.

Claims 27-33 are newly added.

Claims 1-33 are pending.

Claims 7-26 are withdrawn.

Claims 1-6 and 27-33 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-6 remain rejected, and claims 28 and 30-33 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed February 27, 2003.

Applicant's arguments filed June 23, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is rendered moot by the amendments to the claims and specification (reply page 12).

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The amendments to the claims and specification do not overcome the rejection because the specification does not describe or characterize any protein other than a murine dihydrofolate reductase enzyme whose fragments can exhibit a detectable activity when associated with each other in the context of a protein fragment complementation assay. This description does not constitute a substantial portion of the genus that comprises nucleotide sequences coding for a first fusion product comprising (a) a first fragment of any first protein of any type from any source whose fragments can exhibit a detectable activity when associated and (b) a first protein-protein interacting domain; and (2) coding for a second construct coding for a second fusion product comprising (a) any second fragment of said first protein and (b) a second protein-protein interacting domain that can bind (1)(b).

Claims 1-6 remain rejected, and claims 28 and 30-33 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of expressing protein fragment complementation assay interacting partners in plant material comprising (A) transforming plant material with (1) a first construct coding for a first fusion product comprising (a) a first fragment of a murine dihydrofolate reductase enzyme divided into two fragments whose two fragments can exhibit a detectable enzymatic activity when associated with each other and (b) a first protein-protein interacting domain; and (2) a second construct coding for a second fusion product comprising (a) the second fragment of said enzyme and (b) a second protein-protein interacting domain that can bind (1)(b); culturing said material in the presence of fluorescent substrate and under conditions allowing expression of said PCA interacting partners, and (C) detecting said enzymatic activity by fluorescence microscopy, spectrofluorometry, FACS analysis or a fluorescence-detecting video system, including methods in which the

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interaction of said protein-protein interaction domains is facilitated by the addition during culturing of an inducer that specifically induces the binding of said protein-protein interaction domains, does not reasonably provide enablement for other methods of expressing protein complementation assay interacting partners in plant material that utilize other types of first molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed February 27, 2003.

Applicant's arguments filed June 23, 2003, have been fully considered but they are not persuasive.

Applicant argues that the specification is enabling in light of the fact this application now claims status as a CIP of US serial number 09/017,412, issued as U.S. Patent No. 6,270,964, which provides sufficient guidance as to the selection of a reporter molecule, as well as examples of the types of reporters that are desirable. Applicant also argues that exemplification is not required by statute where there is sufficient guidance in the specification (reply page 12).

The Examiner maintains that the status of the instant application as a CIP of US serial number 09/017,412, issued as U.S. Patent No. 6,270,964, does not provide sufficient guidance to enable the full scope of the claims, as U.S. Patent No. 6,270,964 neither claims nor exemplifies any method of expressing any type of protein fragment complementation assay interacting partners in plant material. The Examiner further acknowledges that exemplification is not required by statute, but maintains that the specification does not provide sufficient guidance to enable the full scope of the claims, because the ability of molecular fragments to exhibit a

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detectable activity when associated with each other in the context of a protein fragment complementation assay is unpredictable.

Claim 1, and claims dependent thereon, remain rejected, and new claims 31 and 32 are rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “interacting partners”, for the reasons of record set forth in the office action mailed February 27, 2003.

Applicant's arguments filed June 23, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is rendered moot by the amendments to the claims and specification (reply page 12).

The rejection is not rendered moot by the amendments to the claims and specification because while the amendments do clarify the meaning of the acronym “PCA” and what constitutes a “partner”, they do not clarify the nature of the interaction between the partners.

Claim 1, and claims dependent thereon, remain rejected, and new claim 31 is rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “whose fragments can exhibit a detectable activity when associated”, for the reasons of record set forth in the office action mailed February 27, 2003.

Applicant's arguments filed June 23, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is rendered moot by the amendments to the claims and specification (reply page 12).

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The rejection is not rendered moot by the amendments to the claims and specification because the amendments do not clarify which fragments exhibit a detectable activity when associated, as the amendments are not specifically directed to which fragments exhibit a detectable activity when associated.

Claim 1, and claims dependent thereon, remain rejected, and new claim 31 is rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “a detectable activity”, for the reasons of record set forth in the office action mailed February 27, 2003.

Applicant's arguments filed June 23, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is rendered moot by the amendments to the claims and specification (reply page 12).

The rejection is not rendered moot by the amendments to the claims and specification because the amendments do not clarify the nature of the activity to be detected, as the amendments are not specifically directed to the nature of the activity to be detected.

Claim 1, and claims dependent thereon, remain rejected, and new claim 31 is rejected, under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, for the reasons of record set forth in the office action mailed February 27, 2003.

Applicant's arguments filed June 23, 2003, have been fully considered but they are not persuasive.

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Applicant argues that the rejection is rendered moot by the amendments to the claims and specification (reply page 12).

The rejection is not rendered moot by the amendments to the claims and specification because part (C) of claim 1 as amended requires directly or indirectly testing for reconstitution of an activity when protein fragments are associated, but the claim recites no steps by which this may be accomplished.

Claim 4, and claims dependent thereon, remain rejected, and new claim 33 is rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “where an inducer is added to facilitate the interaction of said protein-protein interaction domains”, for the reasons of record set forth in the office action mailed February 27, 2003.

Applicant's arguments filed June 23, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is rendered moot by the amendments to the claims and specification (reply page 12).

The rejection is not rendered moot by the amendments to the claims and specification because while the amendments do clarify what is being induced by the inducer and at what step of the method an inducer would be added in order to achieve the desired results, the amendments do not clarify in what way the interaction of the protein-protein interaction domains is being facilitated, as the amendments are not specifically directed to the facilitation of the interaction of the protein-protein interaction domains.

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Currently amended claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “said detectable product”, as there is insufficient antecedent basis for this limitation in claim 1 from which claims 4 and 5 depend.

Currently amended claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “said detection means”, as there is insufficient antecedent basis for this limitations in claims 1 and 4 from which claim 5 depends.

Currently amended claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “said enzyme reporter molecule”, as there is insufficient antecedent basis for this limitations in claims 1 and 4 from which claim 6 depends.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Claims 1-6 and 28-33 are deemed free of the prior art, due to the failure of the prior art to teach or suggest a method of expressing PCA interacting partners in plant material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
September 22, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

